

Special Report: MHPAEA Regulations



Operational Analysis of the Mental
Health Parity and Addiction Equity
Act Interim Final Rule

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Introduction

This *Special Report* provides a preliminary analysis of the Mental Health Parity and Addiction Equity Act (MHPAEA) Interim Final Rule and regulations. It is written for the benefit of diverse audiences including health plans, payers, state and federal agencies, legislators, mental health and substance use disorder providers, consumer advocates and other stakeholders in the healthcare and health insurance domains. In marked contrast to the highly polarized debate on health care reform currently in process, the MHPAEA was sponsored in a bi-partisan fashion and signed into law by then President George W. Bush. It evolved from more than a decade of earlier state and federal legislation and large scale research, as well as impassioned advocacy, negotiation and compromise between legislators, civil rights and patient advocates, the medical community, the mental health and substance use disorder treatment communities, the recovery community, business, commerce, and health insurance stakeholders. The MHPAEA is a remarkable achievement for all Americans touched by mental health and substance use issues and their many constituencies, as well as an historic example of good policy being enacted through good legislation. The IFR ushers that policy into effect, and this *Report*, drawing upon the same spirit of cooperation and mutual interest that produced the law, aspires to make the implementation process more informed and effective for all who are involved.

The *Report* is organized to provide the reader with a detailed summary of the regulations; and an in-depth review of the operational and strategic implications of the Interim Final Rule and regulations from the viewpoint of Plans, Payers and Providers; a review of the challenges and unanswered questions that remain as the MHPAEA is implemented; and the opportunities that are available to stakeholders in the field. The goal is to provide readers with the preliminary analysis necessary to determine their immediate next steps in their respective roles. Collectively, the team of authors that prepared this *Report* represents a wide range of expertise and experience in all domains of the health care and coverage arena. They have endeavored to provide suggestions that are objective, reliable and timely.

Highlights of Federal Parity Regulations

Background and Purpose of the Parity Regulations:

- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) became Public Law 110-343 in October 2008
- The MHPAEA prohibits group health plans that currently offer coverage for drug and alcohol addiction and mental illness from providing those benefits in a more restrictive way than other medical and surgical procedures covered by the plan
- The MHPAEA rule and accompanying guidance, issued by the Departments of Health and Human Services, Labor and Treasury (the Departments), is intended to provide greater clarity and guide implementation of the MHPAEA
- In addition to the specific language of the rule, the Departments released guidance including a preamble discussion that defines certain terms and explains how the rule was formulated; the rule also includes numerous specific examples of practices that would and would not meet the requirements of the MHPAEA statute and regulations
- The Departments state that they expect the MHPAEA to affect approximately:
 - 111 million participants in 446,400 ERISA-covered group health plans
 - 29 million participants in the estimated 20,300 public, non-federal employer group health plans sponsored by State and local governments

- 460 health insurance issuers providing substance use disorder (SUD) or mental health (MH) benefits in the group health insurance market
- 120 Managed Behavioral Healthcare Organizations (MBHOs) providing SUD or MH benefits to group health plans

Status of and Process for the MHPAEA Rule:

- The MHPAEA rule was published in the Federal Register Tuesday, February 2nd
- The rule was issued as “interim final”; this includes a 90-day public comment period which closes May 3rd; the Departments identify specific areas on which they would like public comment (listed below)
- Despite being issued as “interim final,” the rule will become effective April 5th. The regulatory guidance states that, until they go into effect, group health plans/issuers must make good-faith efforts to comply with the regulatory requirements
- Group health plans and issuers with plan years beginning on or after July 1, 2010 will be required to comply with the MHPAEA and accompanying regulations
- The rule does not address every area of the MHPAEA and the accompanying guidance makes clear that additional rules will be issued on specific topics; for example, while acknowledging that Medicaid managed care plans offering SUD or MH services must comply with the MHPAEA, the Departments state that this rule does not apply to those plans and that additional guidance will later be given by the Centers for Medicare and Medicaid Services (CMS)
- The citations for the MHPAEA regulations are:
 - 26 CFR Part 54 (Department of Treasury’s Internal Revenue Service regulations)
 - 29 CFR Part 2590 (Department of Labor’s Employee Benefits Security Administration regulations)
 - 45 CFR Part 146 (Department of Health and Human Services Center for Medicare and Medicaid Services regulatory code)

Discussion of the Intersection of State Laws with the MHPAEA:

- The regulations affirm that the MHPAEA does not preempt any State laws except those that would prevent the application of the MHPAEA
- The guidance states that the Departments have tried to “balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide uniform minimum protections to consumers in every State.”
- The regulations also state that, “State insurance laws that are more stringent than the federal requirements are unlikely to ‘prevent the application of the MHPAEA,’ and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.”

Scope of Services/Categories of Care Not Defined by the Regulations:

- The regulations do not define a scope of services or continuum of care for SUD or MH benefits; the regulations state that group health plans can define which services are covered in MH and SUD benefit packages; those definitions must be consistent with “generally recognized independent standards of current medical practice” which include the Diagnostic and Statistical Manual of Mental Disorders, the International Classification of Diseases, and State guidelines
- The regulations do not define what constitutes inpatient, outpatient or emergency care but leave it up to health plans and State health insurance laws to define those terms; the regulations do require group health plans to apply these terms uniformly for medical/surgical benefits and SUD and/or MH benefits

Rule Defines How to Determine whether Financial Requirements and Treatment Limitations Imposed on SUD or MH Benefits Comply with the MHPAEA:

- The MHPAEA statute prohibits group health plans/health insurers offering SUD or MH benefits from applying financial requirements or treatment limitations to SUD or MH benefits that are more restrictive than the predominant financial requirements or treatment limitations applied to substantially all medical/surgical benefits
- The rule defines the terms “predominant” and “substantially all” and gives guidance about how to determine whether financial requirements and treatment limitations imposed on SUD or MH benefits comply with the MHPAEA

Classifications of Benefits are Defined; Parity Analysis Must Compare Financial Requirements/Treatment Limitations Imposed on SUD or MH Benefits with Same Type Imposed on Medical/Surgical Benefits in the Same Classification:

- The rule first identifies six categories of classification of benefits. These six classifications are:
 - Inpatient, in-network
 - Inpatient, out-of-network
 - Outpatient, in-network
 - Outpatient, out-of-network
 - Emergency care
 - Prescription drugs
- The rule specifies that, when examining whether SUD or MH benefits are being offered at parity with other medical/surgical benefits, a financial requirement or treatment limitation must be compared only to financial requirements or treatment limitations of the same type within the same classification
- This review must take place separately (i.e. copayments must be compared with copayments, annual visit limits with annual visit limits) within each above-listed classification
 - Example: The copayment amount charged for an outpatient session of care provided by an in-network SUD service provider must be compared with copayment amounts for sessions of outpatient care provided by other medical/surgical in-network providers
- The rule establishes standards to measure plan benefits so that medical/surgical benefits can be compared with SUD or MH benefits

Rule Discusses Financial Requirements and Treatment Limitations, Including Medical Management Tools, and How They Must Comply with the Parity Requirements:

- Financial requirements are defined as including deductibles, copayments, coinsurance and out-of-pocket maximum
- The rule makes the distinction between quantitative treatment limitations and non-quantitative treatment limitations
 - Quantitative treatment limitations include day or visit limits or frequency of treatment limits
 - Non-quantitative treatment limitations are medical management tools. The regulations include a non-exhaustive list of types of non-quantitative treatment limitations that includes:
 - Medical management standards
 - Prescription drug formulary design
 - Fail-first policies/step therapy protocols
 - Standards for provider admission to participate in a network
 - Determination of usual, customary and reasonable amounts
 - Conditioning benefits on completion of a course of treatment
- The regulations state that group health plans offering benefits for an SU or MH condition or disorder must provide those benefits in each classification for which any medical/surgical benefits are provided; if the plan provides medical/surgical benefits in one of the classifications but does not provide SUD or MH benefits in that classification, that would constitute a treatment limitation
- The regulations state that the processes, strategies, evidentiary standards and other factors used to apply non-quantitative treatment limitations to SUD or MH benefits in a classification have to be comparable to and applied no more stringently than the processes, strategies, evidentiary standards and other factors used to apply to medical/surgical benefits in the same classification. The regulations acknowledge that there may be different clinical standards used in making these determinations.

Discussion of Implications of the MHPAEA on Employee Assistance Programs (EAP):

- The regulations acknowledge that the Departments received a number of questions about whether the MHPAEA requirements apply to the practice of requiring an individual, in order to access his/her MH or SUD benefits, to first exhaust a set number of MH or SUD counseling sessions offered through an employee assistance program (EAP)
- The regulations state that, generally, an EAP providing MH or SUD counseling services in addition to the MH or SUD benefits offered by a major medical program that otherwise complies with parity would not violate the MHPAEA requirements
- However, the regulations also explicitly state that “requiring participants to exhaust the EAP benefits—making the EAP a gatekeeper—before an individual is eligible for the program’s MH or SUD benefits

would be considered to be a non-quantitative treatment limitation” that would be subject to the above-discussed parity analysis to determine compliance with the MHPAEA

- The regulations further state that if other gate keeping processes with similar exhaustion requirements, whether offered through an EAP or not, are not applied to medical/surgical benefits, the exhaustion requirement related to EAPs would violate the rule that non-quantitative treatment limitations be applied comparably and not more stringently to MH and SUD benefits

Rule Defines a “Predominant” Financial Requirement or Treatment Limitation for Purposes of Parity Analysis:

- The rule states that a financial requirement or treatment limitation is predominant if it is the most common or frequent of a type of limit or requirement
- A predominant level (amount) of a type of financial requirement or quantitative treatment limitation is defined as the level that applies to more than one-half of the medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in that classification
- If there is no one level that applies to more than one-half of the medical/surgical benefits that are subject to financial requirements or quantitative treatment limitations in a certain classification, the regulations provide guidance about how this should be determined

Rule Defines What Constitutes “Substantially All” Medical/Surgical Benefits for Purposes of Parity Analysis:

- The rule states that when a financial requirement or quantitative treatment limitation on a medical/surgical benefit applies to at least two-thirds of the benefits in that classification, this is considered to be “substantially all” of those benefits
 - Therefore, if a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical/surgical benefits in a classification, that type of requirement or limitation cannot be applied to SUD or MH benefits in that same classification

Additional Regulatory Provisions Aimed at Providing Parity for SUD and MH Benefits:

- The regulations restate the MHPAEA requirement that, for group health plans/issuers that offer SUD or MH benefits, where out-of-network benefits are provided for medical/surgical benefits they must also be provided for SUD and MH benefits
- The regulations prohibit separate cost-sharing requirements or treatment limitations that apply only to SUD or MH benefits
- The regulations provide guidance on the two MHPAEA disclosure provisions requiring:
 - Criteria for medical necessity determinations for SUD or MH benefits be made available to participants and beneficiaries, and
 - Reasons for denial of reimbursement or payment for SUD or MH services be made available to participants and beneficiaries
- The preamble to the rule acknowledges that some group health plans have lower co-payments for primary care providers than for specialists and that often SUD and MH providers are defined as specialists; the guidance makes clear that there cannot be a separate classification of generalists and specialists in determining whether certain financial requirements or treatment limitations meet the MHPAEA parity requirements
- The guidance prohibits insurers from setting up separate plans or benefit packages to try to avoid complying with the MHPAEA requirements; the guidance states that separately administered benefit packages should be considered as a single plan
- The rule prohibits plans from applying cumulative financial requirements (such as deductibles) or cumulative quantitative treatment limitations for SUD or MH benefits in a classification that accumulates separately from any cumulative financial requirements or cumulative quantitative treatment limitations established for medical/surgical benefits in the same classification

Application of the Parity Requirements to Prescription Drugs:

- The regulations state that the MHPAEA parity requirements apply to prescription drug benefits
- To determine whether a group health plan/issuer is imposing unfair financial requirements on certain drugs prescribed for SUD or MH conditions, the regulations state that financial requirements imposed on drugs prescribed for the treatment of an SUD or MH condition must be compared with those imposed on other prescription drugs in the same tier in which the prescription drug is classified

- The regulations state that if a plan imposes different levels of financial requirements on different tiers of prescription drugs based on “reasonable factors” and without regard to whether a drug is generally prescribed for medical/surgical benefits or SUD or MH benefits, the parity requirement is satisfied

Areas Identified as Subject to Future Regulatory Action:

- The regulations acknowledge that Medicaid managed care plans offering SUD or MH services must comply with the MHPAEA but state that these regulations do not apply to those plans and that additional guidance will be given by the Centers for Medicare and Medicaid Services (CMS)
- The regulations state that additional guidance will be issued “in the near future” concerning the provisions that allow group health plans that experience certain increased costs to be exempt from the MHPAEA requirements

Solicitation for Public Comments:

- In addition to seeking general comments in response to the MHPAEA regulations, the Departments identify a number of areas where they would like public comment including:
 - Whether additional examples of non-quantitative treatment limitations and how the parity analysis would be applied to these medical management tools would be helpful
 - Whether and how the MHPAEA addresses the issue of scope of services/continuum of care
 - Which clarifications would help to ensure compliance with disclosure requirements for medical necessity criteria and denials of SUD or MH benefits
- The 90-day public comment period closes on May 3, 2010

Operational Implications of the Interim Final Rules

This *Report* has identified fifteen (15) aspects of the Interim Final Rule (IFR) as most significant to the stakeholder community and explored each from the practical standpoint of health plans, payers and providers of mental health and substance use disorder treatment. The tables below are not presented in any meaningful order. Each table in this section begins with a brief selection of regulatory language from the IFR and follows it with comments from our experts and a discussion of the tactical and practical implications for each of the two stakeholders primarily responsible for or impacted by the regulations.

In general, the IFR has an immediate impact on American health insurers, managed care organizations, managed behavioral health organizations, third-party administrators and self-insured employers. While the IFR does not directly apply to Medicaid managed care plans, additional regulatory guidance is forthcoming on how these plans should comply with the MHPAEA. There are others, such as pharmacy benefit managers, utilization management, disease management and case management outsource firms that will be affected as well. In essence, the MHPAEA constitutes insurance reform, therefore, the following sections will underscore that the first and foremost responsibility for implementation falls on those who insure and manage benefits. The impacts on providers are secondary only in terms of timing. Providers of MH and SUD treatment will need to adapt to the conditions created by insurers and those who manage benefits. The findings and implications for plans, payers and providers are summarized below and explored in greater depth in the tables that follow.

Plans and Payers

1. Conduct strategic planning and assess availability of resources and expertise for change effort. Allocate sufficient resources.
2. Review policies and benefit design for compliance with the IFR
3. Modify deductibles, annual and lifetime limits, co-pays and other coinsurance accordingly
4. Review care and medical management tactics for compliance

Providers

1. Conduct strategic planning and assess market conditions, existing network contracts, and resources required for compliance with IFR's impacts on care management and billing as well as expansion into new payer markets and geographic or service areas
2. Assess credentials, certifications and accreditation requirements
3. Convene meetings where possible with plans,

5. Define scope of services in alignment with State law referring to any additional direction from Departments
6. Review network of providers in relation to classification of benefits
7. Review prescription drug formulary design for compliance
8. Conduct underwriting analysis
9. Conduct information system reconfiguration analysis
10. Develop plan participant and provider communications strategy
11. Modify all affected agreements and contracts with vendors, suppliers, agents, and customers
4. Position services relative to classification of benefits and scope of services with State definitions in full view
5. Apply for in-network status where appropriate
6. Negotiate Usual, Customary and Reasonable reimbursement
7. Assess and evaluate business processes, workflow, forms, information systems and staff capabilities
8. Assess and modify care management capabilities in order to comply with new plan/payer medical management standards and guidelines including the ability to document and communicate diagnosis, treatment plans, referrals and care coordination, progress notes and discharge plans
9. Assess and modify billing procedures and systems to optimize electronic billing

Table 1: Effective Date

"These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010"

Comments

- Plans that already made their best faith effort to comply effective January 1, 2010 can continue as-is through the end of year or can make mid-year corrections and amendments within their State, filing new plans with their Department of Insurance that come into greater alignment with these regulations. Plans that begin anytime after July 1, 2010 will need to abide by these regulations immediately.
- The window of opportunity for compliance has only recently opened with the release of the regulations. In effect, plans and payers have fewer than six months to reconfigure plan policies, processes and systems or between six and eleven months to come into compliance. Some plans and payers may find that aspects of this effort are challenging in terms of systems change and adoption of new business processes. Whether a managed behavioral health carve-out is in effect or not some plans may find that they require additional subject matter expertise and interim staffing.

Plan & Payer Implications

1. Plans and payers need to consider both the strategic and near term implications of full implementation
2. Plans are encouraged to make as much progress as possible toward implementation within this first year; fines for non-compliance are prohibitively expensive at \$100 /member/day
3. Plans concerned about medical management and professional standards should seek the advice of experts
4. Plans should communicate implementation plans as soon as possible with members and providers.
5. Facilitating communication early among differing provider types (mental health, medical, pharmacy) and functions

Provider Implications

1. Participating providers can expect that claiming will require keeping pace with plans and payers in terms of acceptable code sets and electronic data interchange (EDI). Additionally, medical and utilization management processes are subject to considerable change depending upon the current practices of plan partners so providers will find it beneficial to keep track of operational changes.
2. Providers seeking to join networks will want

(administrative vs. clinical) overcomes resistance and builds necessary collaboration.	to take this opportunity to update their credentials, understand how Usual, Customary and Reasonable rates are determined locally, contact plans and payers and request applications.
6. Plans should consider how they will develop organizational leadership capacity for full deployment.	

Table 2: Addition of Substance Use Disorders (SUD)

“Among the changes enacted by MHPAEA is an expansion of the parity requirements for aggregate lifetime and annual dollar limits to include protections for substance use disorder benefits. Prior law specifically excluded substance abuse or chemical dependency benefits from those requirements. Consequently, these regulations amend the meanings of medical/surgical benefits and mental health benefits (and add a definition for substance use disorder benefits). Mental health benefits and substance use disorder benefits are benefits with respect to services for mental health conditions and substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. These regulations further provide that the plan terms defining whether the benefits are mental health or substance use disorder benefits must be consistent with generally recognized independent standards of current medical practice.

This requirement is included to ensure that a plan does not misclassify a benefit in order to avoid complying with the parity requirements.”

Comments

- This language expands the former working definition of parity to include substance use disorders (SUD). Because SUD conditions and treatment are not well understood by many non-clinicians, plans are urged to consult with experts. Doing so will help avoid plan design decisions that may prove more costly in terms of medical cost-offset in the long-term. There is certainly ample scientific evidence confirming that SUDs are in fact diagnosable and treatable conditions. SUD treatment is not prohibitively expensive if and when it is appropriate to the needs of the individual.
- Plans will also need to review relevant State law in order to accurately define benefits.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Plans are encouraged to consult with experts in order to more fully understand the current medical practice where SUD is concerned. ASAM Certified Addictionologists (physicians with specialized training) can be especially helpful in this regard and in the case of co-occurring disorders. 2. Plans are encouraged to meet with their State's agency or department dedicated to mental health and/or alcohol and drug abuse/substance abuse in order to understand how the public sector has managed best practices, services, and providers in the recent past. These agencies can be very helpful in building the capacity to treat SUD. 3. Plans can review State law regarding benefits for SUD as a function of their overall compliance effort. 	<ol style="list-style-type: none"> 1. Non-participating SUD treatment providers are encouraged to update their credentials and contact local plans and payers in order to become familiar with their expectations and to review service offerings. 2. SUD providers are encouraged to re-examine notions of usual, customary and reasonable (UCR) with revenue management experts and to enter into network contracting where advantageous. 3. Providers can benefit by collaborating and integrating with mental health and primary care wherever feasible. 4. SUD providers – particularly those whose business interests have largely been tied to public sector funding – are encouraged to implement practice management and billing systems capable of electronic data interchange (EDI) at the earliest possible opportunity.

Table 3: Generally Recognized Independent Standards of Current Medical Practice

“The word “generally” in the requirement “to be consistent with generally recognized independent standards of current medical practice” is not meant to imply that the standard must be a national standard; it simply means that a standard must be generally accepted in the relevant medical community. There are many different sources that would meet this requirement. For example, a plan may follow the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of

the International Classification of Diseases (ICD), or a State guideline. All of these would be considered acceptable resources to determine whether benefits for a particular condition are classified as medical/surgical, mental health, or substance use disorder benefits.”

Comments

- Plans and payers are at liberty to make these kinds of determinations locally with the understanding that their plan policies will be consistent with *generally recognized independent standards of current medical practice*. Plans and payers may instinctively gravitate to the American Medical Association (AMA) and the American Psychiatric Association as resources. Plans, payers and employers are encouraged to seek broader input from various MH and SUD organizations and experts prior to finalizing standards. Selecting a too narrow set of standards may exclude services that over the long term are in a plan’s best interest.
- Many providers – particularly new entrants - will find that certain specific credentialing and accreditation standards will be enforced in the commercial health plan sector and that their participation in this market will require strengthening credentials and capabilities.
- HHS/SAMHSA can provide direction to further the cause of national standards for the treatment of MH and SUD by preparing employer-friendly materials describing best practices and standards.

Plan & Payer Implications

1. Plans will need to assess and evaluate their various non-quantitative medical management tools to assure alignment with recognized standards. Many plans and payers – relatively new to expanded behavioral health coverage – may not be equipped and others may have relied on their EAP to serve as a gatekeeper, an arrangement that is no longer permitted.
2. Fully considering the pros and cons of buying or building such capacity is probably in the best interest of many plans at this juncture.

Provider Implications

1. “Accepted in the relevant medical community” language can be both a positive development and a potential roadblock for some SUD providers in particular. The field will need to advocate for the inclusion of their own relevant standards in discussion with commercial and employer based plans though some providers will need to accept that certain credentials and accreditations must apply in the commercial sector. Some providers will be faced with difficult business decisions regarding credentials and accreditation.
2. Providers are urged to familiarize plans and payers with their treatment, services, methodologies and tools. Many times, the underpinnings of effective MH and SUD treatment are better known to the community behavioral health sector and need to be shared openly with payers who may be less familiar with standards such as ASAM Patient Placement Criteria or the importance of Child Psychiatrists in the treatment of Serious Emotional Disturbance (SED).

Table 4: Non-Quantitative Treatment Limitations

“These regulations provide that the parity requirements in the statute apply to both quantitative and non-quantitative treatment limitations. A quantitative treatment limitation is a limitation that is expressed numerically, such as an annual limit of 50 outpatient visits. A non-quantitative treatment limitation is a limitation that is not expressed numerically, but otherwise limits the scope or duration of benefits for treatment...Such non-quantitative provisions are also treatment limitations affecting the scope or duration of benefits under the plan. These regulations provide an illustrative list of non-quantitative treatment limitations, including:

- *medical management standards;*
- *prescription drug formulary design;*
- *standards for provider admission to participate in a network;*
- *determination of usual, customary, and reasonable amounts;*
- *requirements for using lower-cost therapies before the plan will cover more expensive therapies (also known as fail-first policies or step therapy protocols);*

- conditioning benefits on completion of a course of treatment...

...The phrase, “applied no more stringently” was included to ensure that any processes, strategies, evidentiary standards, or other factors that are comparable on their face are applied in the same manner to medical/surgical benefits and to mental health or substance use disorder benefits... A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation”

Comments

- The regulations devote a considerable amount of attention to non-quantitative limitations in order to assure that plans and payers do not arbitrarily limit care. The regulations identify six general categories of such restrictions and state that practices in each of the six categories cannot be any more stringent where MH and SUD are concerned than they are for medical and surgical concerns.
- The definition of non-quantitative treatment limitations impacts health plan operations across the board and will require considerable review, planning, design and implementation.
- A review of what constitutes Usual, Customary and Reasonable (UCR) may prove to be very beneficial to some providers and facilities though it will require developing expertise in this area.
- To the extent that plan members can be admitted directly to the level of care they require, plan members and providers will require education concerning a plan’s medical management processes and continuity of care while level of care guidelines will become very important to both providers and payers.
- The requirement that completion of treatment be evaluated is another very big change for those plans that have heretofore deemed that any discharge *Against Medical Advice* is not covered. This dimension will need to be handled carefully by all stakeholders so as not to become abused.
- Much of this language reflects positive developments for people with MH and SUD treatment needs, their families and providers. However, it still invites the opportunity for plans to explore guidelines and the risk is that some plans and payers will gravitate toward strictly medical approaches whereas the behavioral healthcare field relies on defining what is “clinically” appropriate. The distinction between “clinical” and “medical” necessity and standards will need to be handled very carefully by all stakeholders. Plans, payers and providers should expect this dimension to be contentious in some cases as various interest groups call into question the validity of certain practices and standards.
- One segment of the rule reminds consumers and providers to appreciate that all people and circumstances are unique and that some medical management decisions – while not agreeable to the consumer or provider – will be in accord with medical guidelines and hence in compliance with regulations. Disagreement and adverse determinations do not and will not always involve discriminatory practices.
- Regulatory oversight, in light of the remaining ambiguity and subjectivity, may prove difficult depending upon the State and any existing MH and/or SUD coverage mandates.
- The last statement in the section above - *A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation* – provides very clear direction that plans and payers can exercise their discretion when establishing their list of covered conditions and disorders.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Payers are encouraged to take advantage of the opportunity to comment. 2. Health plans and payers can closely evaluate the practices of their MBHO carve-out vendors in any one of the six “classifications of benefits” to ensure they are no more stringent than the plan’s practices for medical benefits. Some plans may be better able to assure themselves of consistency and alignment by in-sourcing or carving-in some of the medical management processes performed by MBHOs though this determination should be evaluated very carefully with vendors. Plans and payers will want to enlist the guidance of experts in reviewing and evaluating their various practices and standards and may want to explore the adoption of more contemporary or comprehensive tools. 	<ol style="list-style-type: none"> 1. Providers are encouraged to take advantage of the opportunity to comment on the IFR 2. Providers are urged to familiarize plans and payers with their treatment, services, methodologies and tools. 3. Providers are encouraged to carefully evaluate the risks and rewards of joining local and regional networks. 4. Prepare for Utilization Management and develop streamlined processes and forms to accelerate turn-around time 5. Consider developing the capacity to serve children and families, co-morbid medical conditions, co-locating with primary care and

<ol style="list-style-type: none"> 3. The review of MH and SUD conditions, providers and coverage may have a direct impact on staffing levels and types of staff 4. Modifications to Medical Management practices must be reflected in technology and systems 5. Plans and their PBM administrators need to evaluate the equity and parity of formulary design and make adjustments accordingly. Changes need to be reflected in everything from underwriting to marketing and claims reporting. 6. Plans are strongly encouraged to open networks and re-examine standards for credentials and accreditation. Plans and payers should meet with State agencies and community behavioral health (MH and SUD) providers in order to discover the value they can deliver in the treatment of SMI and SUD. The vast majority of treatment for the seriously mentally ill and those suffering from SED and SUD has thus far been delivered by community providers. While standards and criteria they utilize may be a departure from the norm for some plans, their experience and expertise in the efficient treatment of MH and SUDs can be an invaluable resource. 7. Meet with non-traditional providers as well as existing providers to openly review UCR. Review rate-setting with Compliance and Finance. Changes need to be reflected in underwriting, contracts, and claims processing systems. 8. Review Medical Management practices for the practice of "Fail-First" or Step Therapy protocols as well as references to making coverage contingent upon completion of a course of treatment and contrast each against its medical counterpart. Make changes in policy, process and systems accordingly. Make any remaining plan certificate or SPD modifications accordingly. 	<p>joining a local Patient-Centered Medical Home initiative</p> <ol style="list-style-type: none"> 6. Obtain adequate revenue management expertise in order to effectively negotiate and set rates with payers and plans and develop the capabilities and systems to submit EDI-compliant billings to multiple payers
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Table 5: Classification of Benefits

"Classification of benefits. Paragraph (c)(1) cross-references the term "classification of benefits" in paragraph (c)(2)(ii). Paragraph (c)(2)(ii) describes the six benefit classifications and their application, which are discussed later in this preamble. These regulations provide that the parity requirements for financial requirements and treatment limitations are applied on a classification-by-classification basis...These regulations specify, in paragraph (c)(2)(ii), six classifications of benefits: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs..... If a plan does not have a network of providers for inpatient or outpatient benefits, all benefits in the classification are characterized as out-of network... If a plan provides benefits for a mental health condition or substance use disorder in one or more classifications but excludes benefits for that condition or disorder in a classification (such as outpatient, in-network) in which it provides medical/surgical benefits, the exclusion of benefits in that classification for a mental health condition or substance use disorder otherwise covered under the plan is a treatment limitation. It is a limit, at a minimum, on the type of setting or context in which treatment is offered... These regulations do not define inpatient, outpatient, or emergency care. These terms are subject to plan design and their meanings may differ from plan to plan. Additionally, State health insurance laws may define these terms. A plan must apply these terms uniformly for both medical/surgical benefits and mental health or substance use disorder benefits. However, the manner in which they apply may differ from plan to plan..."

Comments

- This section attempts to assure parity between medical and MH/SUD benefits across different classifications of benefits. It ensures, for example, that inpatient medical co-pays or limits are not imposed on outpatient mental health services. Unfortunately, the notable absence of definition around scope of services will complicate matters for health plan managers.
- It specifies that coverage of MH and SUD in one classification necessitates coverage in the other classifications if a

corresponding medical/surgical benefit exists in that class. In other words, a plan cannot offer medical coverage in the Inpatient, In-Network classification and not also provide coverage on some level (in or out-of-network) for MH and SUD if it also generally provides coverage for MH and SUD in the other classifications.

- Managed Behavioral Health Organizations (MBHOs) will be required to modify plans and business rules in their systems accordingly, normalizing plan designs with their health plan counterparts.
- MH and SUD providers may find that the resulting variability in benefits is overwhelming to keep track of and to integrate with their practice management and billing systems. The potential for complexity will require greater expertise in revenue management and greater capability in terms of billing.
- There is additional reference to the provision of out-of-network coverage where a particular benefit exists (by virtue of these regulations and the existence of medical coverage in a class) yet no network exists. The language is clear that if a plan has any other classification coverage for MH and SUD and offers medical coverage in a classification yet has no corresponding network of MH and SUD providers, then that plan shall at a minimum cover care in that class with Out-of-Network benefits.
- Leaving the definition of classes/levels of care to States and plans will result in great complexity. For instance, two people residing in two states suffering from the same acuity of an identical disorder or diagnosis may have benefits approved for very different types of treatment services despite what evidence based practice would dictate. This language, for example, enables plans to define Inpatient only in such a way as to cover medically-necessary stays in a JCAHO accredited facility for conditions that may have been more efficiently and effectively treated in a therapeutic group home or residential treatment facility.
- There is no guidance in the regulations for the types of treatment that lie outside the six classifications they provide.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Whereas many MH/SUD benefits in the past have been relatively simple to administer, plan and system configuration, medical management, and day-to-day claiming/processing will now be more complex processes. 2. Some plans are capable of clearly stating what is covered and what is not but many will require direction. Plans are advised to consider that the medical cost-off-set that results from a too-narrow definition of coverage is not in their best interest, and are encouraged to seek guidance in defining classifications of benefits for MH/SUD conditions and services. 3. Plans are also urged to meet and discuss openly the classification of benefits related to the care of Serious and Persistent Mental Illness (SPMI), SED and SUD with the experts that have long been responsible for those services. They can be found within the community of providers and within State agencies responsible for MH and SUD. This is an excellent opportunity to integrate, "braid" and "blend" providers, services and potentially the funding that exists for these chronic and complex conditions. This is particularly true in the case of court-ordered treatment, admissions to State Hospitals and Assertive Community Treatment (ACT). 	<ol style="list-style-type: none"> 1. Bearing in mind that a single health plan or employer can offer many different plan designs, providers should anticipate a great deal of complexity and should plan to make investments in revenue management and information systems that will allow them to navigate that complexity successfully. 2. Providers that can begin advocating for their services with the State Department of Insurance and local plans' Provider Relations staff/Medical Director are encouraged to do so. This language and this effort to normalize classifications of care will require openness and willingness in discussions between stakeholders. 3. Providers are similarly encouraged to explore horizontal and vertical alliances that deliver greater strength in terms of representation, operations and administration. Other providers may use this opportunity to entertain strategic joint ventures as well as mergers and acquisitions.

Table 6: Scope of Services (Continuum of Care)

"The Departments recognize that not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical conditions. These regulations do not address the scope of services issue. The Departments invite comments on whether and to what extent MHPAEA addresses the scope of services or continuum of care provided by a group health plan or health insurance coverage."

Comments	
<ul style="list-style-type: none"> This language is directly related to the Classification of Benefits section above. The Departments acknowledge that they are not clarifying scope of services beyond the discussion of Classification of Benefits at this point in time, effectively leaving decisions surrounding service types, levels and definitions to plans and states. The additional comment period is helpful but will lead to severe time constraints and communication issues for plans and payers in the final half of the year. Among the issues that may be overlooked is the opportunity to more efficiently treat complex co-morbid conditions that exacerbate plan costs. The coordination of care between medical and MH/SUD systems has been proven effective, but certain plan designs may create unintended barriers to coordinated treatment. There is a risk that plan definitions may be too narrow to include clinically-appropriate services and, therefore undermine the effective, well-rounded person-centered care of highly complex conditions like SPMI and SED in children. It is critical that both providers and plans take advantage of the open comment period, and should jointly arrive at a set of recommendations where possible. 	
Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> Plans and payers are encouraged to work closely with clinical experts and their State to adopt services and a continuum of care that is commensurate with the medical and clinical needs of their members suffering from SPMI, SMI, SED and SUD. Plans are urged to submit comments to the Federal Departments in a timely fashion. 	<ol style="list-style-type: none"> Providers are strongly urged to review their services with the State Department of Insurance and local plans and payers, advocating for inclusion at this critical point in time. Providers are also encouraged to submit their comments to the Federal Departments in a timely manner.

Table 7: Gatekeeper Role of EAP

“Requiring participants to exhaust the EAP benefits – making the EAP a gatekeeper –before an individual is eligible for the major medical program’s mental health or substance use disorder benefits is a non-quantitative treatment limitation subject to the parity requirements. Consequently, if similar gatekeeping processes with a similar exhaustion requirement (whether or not through the EAP) are not applied to medical/surgical benefits, the requirement to exhaust mental health or substance use disorder benefits available under the EAP would violate the rule that non-quantitative treatment limitations be applied comparably and not more stringently to mental health and substance use disorder benefits.”

Comments	
<ul style="list-style-type: none"> Plans and payers (employers and MBHOs included) cannot use EAP as the gatekeeper to MH/SUD benefits since the EAP does not serve in that capacity for all other medical and surgical conditions. This will be a challenge for EAP vendors, many of which have evolved to fill a gatekeeping function. EAP agreements and scope of service will necessarily have to change and EAP vendors will wish to solidify their position as an important service for Human Resource and Personnel concerns – their original form and function. EAP plays a vital role in the identification and remediation of workplace concerns including violence in the workplace, conflict management, responding to substance abuse, and critical incident debriefing and related services. EAP also provides employees and their family members with important access to services that are non-clinical in nature yet have a direct and positive impact on morale, absenteeism, presenteeism and other workplace dynamics. EAPs have absorbed much of the costs related to people seeking basic outpatient counseling so underwriters will want to estimate the impact in health plan utilization as a result of this change. The largest MBHOs will recognize the opportunity this creates in the market. Small and regional standalone EAP vendors may suffer losses and find it advantageous to explore mergers and acquisitions. 	
Plan & Payer Implications	Provider Implications
1. Plans and payers that use an EAP as a gatekeeper will need	1. This may represent an operational change

<p>to address their agreements and either in-source that process or find a capable MBHO. This may prove to be a cost-savings opportunity for some plans and payers.</p> <ol style="list-style-type: none"> 2. This change will require communication with plan members who will have grown accustomed to contacting their EAP for service authorization and referrals. Continuity of services will be important to maintain during any transitions. 3. Plans and payers are reminded that the EAP often provides a 24-hour hotline to screen, assess and refer callers. That important capability – handling crisis calls on weekends and after-hours - will need to be addressed if and when plans decide to in-source the gatekeeping function. MBHOs have this capability. 4. MBHOs will be required to align their medical management processes with those of the broader health plan as described earlier. 	<p>for some providers who have grown accustomed to seeking prior authorization and referrals from local and regional EAPs.</p> <ol style="list-style-type: none"> 2. Providers will want to communicate directly with plan and payer provider relations and network administrators to better understand new processes.
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Table 8: Single Plan

“The new combined rule in these regulations does not use the term benefit package. Instead, it provides that (1) the parity requirements apply to a group health plan offering both medical/surgical benefits and mental health or substance use disorder benefits, (2) the parity requirements apply separately with respect to each combination of medical/surgical coverage and mental health or substance use disorder coverage that any participant (or beneficiary) can simultaneously receive from an employer’s or employee organization’s arrangement or arrangements to provide medical care benefits, and (3) all such combinations constitute a single group health plan for purposes of the parity requirements. This new combined rule clearly prohibits what might have been formerly viewed as a potential evasion of the parity requirements by allocating mental health or substance use disorder benefits to a plan or benefit package without medical/surgical benefits (when medical/surgical benefits are also otherwise available)..

...Health insurance issuers. These regulations make a change regarding applicability with respect to health insurance issuers. Both the MHPA 1996 regulations and these regulations apply to an issuer offering health insurance coverage. The MHPA 1996 regulations provide that the health insurance coverage must be for both medical/surgical and mental health benefits in connection with a group health plan; the rule in these regulations provides that the health insurance coverage must be for mental health or substance use disorder benefits in connection with a group health plan subject to MHPAEA under paragraph (e)(1). Thus, under these regulations, an issuer offering health insurance coverage without any medical/surgical benefits is nonetheless subject to the parity requirements if it offers health insurance coverage with mental health or substance use disorder benefits in connection with a group health plan subject to the parity requirements. In addition, under these regulations, the parity requirements do not apply to an issuer offering health insurance coverage to a group health plan not subject to the parity requirements...

Comments

- The Departments have made this rule clear: all medical care benefits provided by an employer or employee organization constitute a single health plan. That health plan will need to comply with the full extent of the rules and regulations if MH and SUD benefits are provided.
- This rule speaks to the approach some employers were attempting which would have seen their MH/SUD carve-out treated as a distinct benefit, separate from the health plan and, therefore, not subject to the MHPAEA. Employers who have taken this approach will need to review and modify their plans accordingly as well as any agreements they may have in place with carve-out vendors..
- To clarify, the Departments included this helpful language in the regulations:
For example, if an employer with a single benefit package for medical/surgical benefits also has a separately administered benefit package for mental health and substance use disorder benefits, the parity requirements apply to the combined benefit package and the combined benefit package is considered a single plan for purposes of the parity requirements. Similarly, if an employer offered three medical/surgical benefit packages, A, B, and C, and a mental health and substance use disorder benefit package, D, that could be combined with each of A, B, and C, then the parity requirements must be satisfied with respect to each of AD, BD, and CD. If the A benefit package had a standard option and a high option, A1 and A2, then the parity requirements would have to be satisfied with respect to each of A1D and A2D.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Employers who have assumed that a carve-out would obviate them from compliance will need to review and amend their plans and MBHO carve-out agreements accordingly..Implications of this change will reverberate through various functional areas. Plans, payers and issuers may want to seek external guidance. 2. A streamlined approach to effectively managing benefits and costs is possible and employers as well as public employee plans are urged not to eliminate MH/SUD coverage. The consequences of such a decision will manifest in medical cost-offset as people with MH and SUD treatment needs seek care in more expensive settings for related co-morbid conditions. The elimination of MH and SUD benefits can be financially devastating to families and potentially very dangerous in terms of mortality. 3. Regional and local MBHOs may find it useful to review their capacity to deliver services in full compliance with the rules and regulations. Agreements may be modified around a different scope of services. Vendors may want to take this opportunity to develop strategic joint ventures with larger, more capable vendors. 	<p>This language has little to no effect on providers.</p>

Table 9: Scope of the Regulations

“Scope. Paragraph (e)(3) of these regulations provides that nothing in these regulations requires a plan or issuer to provide any mental health or substance use disorder benefits. Moreover, the provision of benefits for one or more mental health conditions or substance use disorders does not require the provision of benefits for any other condition or disorder.”

Comments	
<ul style="list-style-type: none"> • The MHPAEA does not mandate MH and SUD coverage. Plans and issuers can decide not to provide any coverage. Public plans (City, County, State employee plans) are exempt from covering MH/SUD – like ERISA plans – if they choose to eliminate coverage altogether. • This language also specifies that coverage for one condition (where many plans have identified 7-10 conditions and disorders they will cover) does not compel or commit plans to the coverage of any other disorders. This final point may become problematic as plans attempt to identify the appropriate mix of conditions and disorders to cover. 	
Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Plans and payers are encouraged to work closely with clinical experts and their State to adopt services and a continuum of care that is commensurate with the medical and clinical needs of their members suffering from SPMI, SMI, SED and SUD. The costs associated with a too-narrow list of covered conditions may result in cost-offset, particularly where co-morbid conditions are concerned. 	<ol style="list-style-type: none"> 1. It will be critical that providers review eligibility at the point of patient registration in order to properly establish the coverage they have. The fact that a patient has health insurance does not guarantee that they have MH and SUD coverage nor does it assure coverage for all conditions and disorders. 2. Providers are encouraged to review patient registration and eligibility verification processes and documentation/information management.

Table 10: Defining Mental Health and Substance Use Disorder Benefits

“Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines)...

...Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).”

Comments

- Plans and issuers can exercise their discretion when defining the terms of benefits with respect to disorders and conditions.
- Plans and issuers can consult generally recognized independent standards of current medical practice such as the most current version of the DSM, the most current version of the ICD, or State guidelines in order to establish and define their terms.

Plan & Payer Implications

1. Plans and payers may consult with experts in order to define their terms for benefits and coverage with regards to certain disorders and conditions.

Provider Implications

1. This language has no immediate bearing on providers except to the extent that it may be helpful to discuss the importance of covering certain conditions and disorders.
2. As discussed above, it will be very important for providers to understand that patients will present with a wide array of benefits and coverage and that information will need to be tracked carefully in practice management and billing systems.

Table 11: Disclosures

“MHPAEA includes two new disclosure provisions for group health plans (and health insurance coverage offered in connection with a group health plan). First, the criteria for medical necessity determinations made under a plan (or health insurance coverage) with respect to mental health or substance use disorder benefits must be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. These regulations repeat the statutory language without substantive change. The Departments invite comments on what additional clarifications might be helpful to facilitate compliance with this disclosure requirement for medical necessity criteria...

... MHPAEA also provides that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available, upon request or as otherwise required, by the plan administrator (or the health insurance issuer) to the participant or beneficiary in accordance with regulations. These regulations clarify that, in order for plans subject to ERISA (and health insurance coverage offered in connection with such plans) to satisfy this requirement, disclosures must be made in a form and manner consistent with the rules for group health plans in the ERISA claims procedure regulations, which provide (among other things) that such disclosures must be provided automatically and free of charge.”

Comments

- This language clarifies that the criteria used for MH and SUD medical necessity determinations made under a plan must be made available to current and prospective plan participants and contracting providers upon request.
- This language also makes it clear that reasons for denial of reimbursement or payment of MH/SUD services must also be made available upon request. These disclosures must be made automatically and free of charge to the plan member making the request.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> Plans and payers with any questions or doubts may want to consult with experts in order to independently validate that their existing medical necessity guidelines and criteria are appropriate for MH and SUD. Plans may be interested in evaluating options and alternatives or may require the help of experts in selecting an appropriate set of tools. Any changes to criteria and guidelines of this nature will be optimized by thorough implementation and training and will necessitate some reconfiguration of systems and business processes Denial codes and reasons may need to be documented and configured in information systems and the process by which plans communicate denials (EOB) will need to be assessed for compliance. 	<ol style="list-style-type: none"> Providers may want to enhance their understanding of medical necessity guidelines and the manner in which they are applied in medical management. Experts – as well as plan provider relations staff - can provide clinical staff with training that streamlines processes. Providers may want to request guidelines prior to beginning to serve patients in order to familiarize themselves and make any necessary business process changes, particularly those that will impact electronic data interchange (EDI) and systems configuration.

Table 12: MH and SUD Providers as Generalists

“These regulations, therefore, do not allow the separate classification of generalists and specialists in determining the predominant financial requirement that applies to substantially all medical/surgical benefits...”

...Under these regulations, if a plan provides any benefits for a mental health condition or substance use disorder, benefits must be provided for that condition or disorder in each classification for which any medical/surgical benefits are provided.”

Comments

- This section answers an important question for plans and providers alike. MH and SUD providers will be subject to the same level of co-pay or coinsurance as their medical counterparts in the determination of benefits. If the co-pay for outpatient, in-network primary care office visits is \$25, then the same co-pay will apply to an outpatient, in-network MH office visit. This change may have an impact on underwriting and plan costs.

Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> Plans and payers will want to review plan policies, provider contracts, fee and reimbursement schedules and claims processing systems and make changes accordingly. Plan member materials, policies and certificates will need to be updated to reflect this change. EOB and remittance advice will need to be modified accordingly. Plans may want to take this opportunity to negotiate UCR and rates with contracting providers. Where plans contract for MH and SUD with MBHOs or other forms of specialty networks, aggregate changes will need to be made. Systems and EDI may require alignment in order to maintain auto-adjudication performance. 	<ol style="list-style-type: none"> Providers will want to properly configure practice management and billing systems to reflect changes in coverage and revenue management. Providers should review systems with any external billing vendors or clearing house in order to maintain EDI performance. Front-office staff, business rules and processes will need to be reengineered and people will require training to adapt to this change.

Table 13: Single Deductible

“Some cumulative financial requirements, such as deductibles and out-of-pocket maximums, involve a threshold amount that causes the amount of a plan payment to change. These regulations clarify that, for purposes of deductibles, the dollar amount of plan payments includes all payments with respect to claims that would be subject to the deductible if it had not been satisfied. For purposes of out-of-pocket maximums, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that were taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-

pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Other threshold requirements are treated similarly... These regulations provide, in paragraph (c)(3)(v), that a plan may not apply cumulative financial requirements (deductibles) or cumulative quantitative treatment limitations to mental health or substance use disorder benefits in a classification that accumulate separately from any such cumulative financial requirements or cumulative quantitative treatment limitations established for medical/surgical benefits in the same classification...

...Some group health plans and health insurance issuers “carve-out” the administration and management of mental health and substance use disorder benefits to MBHOs. These entities obtain cost savings for plan sponsors by providing focused case management and directing care to a broad network of mental and behavioral health specialists (with whom they negotiate lower fees) who ensure that appropriate care for mental health conditions and substance use disorders is provided. When a group health plan or health insurance issuer uses a carve-out arrangement, at least two entities are involved in separately managing and administering medical/surgical and mental health and substance use disorder benefits. The imposition of a single deductible requires entities providing medical/surgical and mental health and substance use disorder benefits to develop and program a communication network often referred to as an “interface” or an “accumulator” that will allow them to exchange the data necessary to make timely and accurate determinations of when participants have incurred sufficient combined medical/surgical and mental health and substance use disorder expenses to satisfy the single deductible.”

Comments

- The IFR unequivocally mandates a single deductible for medical/surgical, MH and SUD. A single deductible will require building new interfaces or accumulators between health plans and their MBHOs.
- Providers and their patients should find that a single deductible marks a significant shift towards simplicity

Plan & Payer Implications

1. Plans and payers will need to review MBHO capabilities with respect to interfaces and accumulators and some will require independent testing, verification and validation.
2. Changes to deductibles may have a profound impact on risk-bearing agreements with networks and MBHOs requiring review, underwriting analysis and changes to capitation agreements. These conditions will lead to a competitive marketplace for MBHOs
3. Plans and their partners might begin to consider the advantages, if any, of in-sourcing claims processing and other functions in order to better manage the entire cycle of medical management and claims processing.

Provider Implications

1. Providers will need to understand the changes to the benefits and coverage applicable to their existing caseload and modify billing processes and systems accordingly.

Table 14: Defining “Predominant” and “Substantially All”

“The first step of these regulations in applying the general parity requirement of MHPAEA is to determine whether a financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification. Regulations issued under MHPA 1996 interpreted the term “substantially all” to mean at least two-thirds (2/3). Under these regulations, a financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of the benefits in that classification...

... If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical surgical benefits in a classification, that type of requirement or limitation cannot be applied to mental health or substance use disorder benefits in that classification. If a single level of a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of medical/surgical benefits in a classification, then it is also the predominant level and that is the end of the analysis. However, if the financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification but has multiple levels and no single level applies to at least two-thirds of all medical/surgical benefits in the classification, then additional analysis is required. In such a case, the next step is to determine which level of the financial requirement or quantitative treatment limitation is considered predominant...

... Under these regulations, the predominant level of a type of financial requirement or quantitative treatment limitation is the level that applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in that classification. If a single level of a type of financial requirement or quantitative treatment limitation applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in a classification (based on plan costs, as discussed earlier in this preamble), the plan may not apply that particular financial requirement or

quantitative treatment limitation to mental health or substance use disorder benefits at a level that is more restrictive than the level that has been determined to be predominant...

... If a plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

*If a plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—
Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or*

Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)”

Comments

- This language represents a fairly complex approach to determining how MH and SUD benefits will be established relative to the Classification of Benefits discussed earlier.
- For each classification, plans must determine which quantitative and non-quantitative limitations apply to approximately two-thirds (2/3) of all medical benefits in order to establish “substantially all”
- In order to define the “predominant” level of coverage in any classification (that applies to substantially all benefits within that classification), plans must determine which quantitative level applies to more than one-half (50%) of medical benefits.
- A plan must be able to demonstrate that a quantitative limitation being applied to MH and SUD benefits in a particular classification is no more stringent than the predominant level of substantially all medical benefits in the same classification.

Plan & Payer Implications

1. Plans and payers will need to review policies and summary plan descriptions to assess the predominant level of substantially all medical benefits and modify MH and SUD coverage accordingly. This change will have impacts across plan design, underwriting, marketing, member communications, customer service and claims processing.

Provider Implications

1. Providers will need to understand the changes made in their existing caseload's benefits and coverage and modify their billing processes and systems accordingly.

Table 15: Prescription Drug Formulary Design

“Special rule for prescription drug benefits with multiple levels of financial requirements. These regulations include, in paragraph (c)(3)(iii), a special rule for applying the general parity requirement of MHPAEA to prescription drug benefits. Consequently, these regulations provide that if a plan imposes different levels of financial requirements on different tiers of prescription drugs based on reasonable factors (such as cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up), determined in accordance with the requirements for non-quantitative treatment limitations, and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or mental health or substance use disorder benefits, the plan satisfies the parity requirements with respect to the prescription drug classification of benefits. The special rule for prescription drugs, in effect, allows a plan or issuer to subdivide the prescription drug classification into tiers and apply the general parity requirement separately to each tier of prescription drug benefits.

For any tier, the financial requirements and treatment limitations imposed with respect to the drugs prescribed for medical/surgical conditions are the same as (and thus not more restrictive than) the financial requirements and treatment limitations imposed with respect to the drugs prescribed for mental health conditions and substance use disorders in the tier.”

Comments

- This section applies the same rules for non-quantitative and quantitative (financial) limitations to prescription drug formulary design as have been applied to all other classifications of benefits
- Plans and their PBM partners cannot impose more stringent or restrictive limitations on MH and SUD drugs in a

given formulary tier than are in place for medical drugs	
Plan & Payer Implications	Provider Implications
<ol style="list-style-type: none"> 1. Plans will need to meet with pharmacy benefit managers to review and assess the current design and make changes accordingly. 2. Plans will need to assess the underwriting impact of this change 3. Plans will need to modify risk-bearing agreements that include MH and SUD prescription drugs in their cost accounting. 	<ol style="list-style-type: none"> 1. Prescribers and acute inpatient facilities will need to understand how the resulting formulary designs impact them and their patients. 2. Some providers will need to understand how this change affects any capitation agreements they have in place that include risk where MH and SUD drugs are concerned.

Challenges and Unanswered Questions

The following sections provide a brief discussion of the challenges, open issues, unanswered questions and the immediate, positive prospects related to the IFR. It is important at this point to remind the reader that the MHPAEA does not directly affect individual and small group health insurance. It is also noteworthy that while the Departments and our legislators have enhanced coverage for many millions of people, they have not obligated public employee health plans representing State, County and local governments to comply with the law and regulations. This is a curious decision which has already resulted in some public employee health plans dropping MH and SUD benefits altogether. Lastly, the IFR does not attend to three veritable pillars of health policy: access, quality and outcomes. It is true that each of these is the individual concern of health plans, issuers and other payers; organizations such as the National Committee for Quality Assurance (NCQA) and the Utilization Review Accreditation Committee (URAC) exist to measure performance in these areas. Nevertheless, it is perhaps a lost opportunity that the MHPAEA did not pursue a common, standardized approach to measuring access, quality and outcomes in MH and SUD care and coverage.

Scope of Services

- The regulations do not define scope of services. For plans in states with mandated mental health or SUD parity or partial parity (applying to specific conditions and disorders), this is less problematic. For ERISA groups who aren't subject to State law and health plans operating in those states with no mandated mental health and/or substance benefits, the challenge lies in deciding which diagnoses, conditions and disorders to cover and which treatment services (and, by extension, providers) to extend benefits to.
- The regulations do not define levels of care, provider types or service levels beyond a broad description or "Classification of Benefits." The regulations also do not address access standards or attempt to assure a clinically appropriate continuum of care. Although the regulations define six classifications of benefits, services such as Targeted Case Management, Intensive Outpatient and Residential treatment are not discussed. The Departments have invited additional comments on *"whether and to what extent MHPAEA addresses the scope of services or continuum of care provided by a group health plan or health insurance coverage"* and plans, payers and providers are encouraged to participate in that process.
- Ambiguity around scope of services exacerbates the complexity of implementation since treatment for many SUD and MH disorders will not have an analogous medical or surgical benefit from which to gauge parity. Clear guidance on the continuum of services will forestall challenges to health plan decisions in this arena, curtailing the risk that denial of certain services will be deemed a *"non-quantitative treatment limitation"* and render a plan non-compliant.
- The Interim Final Rule includes a number of imprecise phrases such as *"generally accepted medical standards,"* which may pose a threat to conditions, services, and providers that do not necessarily meet "medical" standards. Mental health and substance use disorders are diagnosable and individuals with MH and/ SUD respond exceptionally well to treatment; however, these complex chronic disorders are

nuanced and feature behavioral, social and – in the case of children – educational dimensions that are often characterized as clinical or rehabilitative in nature rather than strictly medical. In order to determine covered conditions and appropriate medical management tools, some plans, payers and issuers may rely too heavily on medical standards and overlook the importance of clinical services that are central to recovery.

Financial

- The regulations may not accurately reflect costs related to several implementation concerns. The cost estimates for such activities as building electronic interfaces between claims processing systems and conducting data-intensive review of classifications of benefits across plans on an annual basis appear to be understated.
- Several areas of potential intersection between the public and private systems of care and associated financial implications are not addressed in the regulations. These include:
 - Whether court-ordered treatment will be covered
 - Whether State hospital stays will be a covered service
 - Whether involuntary holds will be a covered service
- While the regulations do address the mechanism by which the cost exemption can initially be invoked, the Departments have stated their intent to issue additional guidance on *“implementing the new requirements for the increased cost exemption under MHPAEA.”* Ongoing administration of the cost exemption will not be feasible for the majority of group plans unless regulations allow the use of actuarial projections of total cost for coverage in future years.
- In light of diverse State laws, a combined deductible, and the potential conflict between health plan autonomy to render coverage decisions and the need to avoid non-quantitative treatment limitations, interpretation of the MHPAEA represents a labyrinth of complexity. Plans and employers that provide benefits across State boundaries have considerable work to do in order to assure compliance.
- Plans and employers have a considerable communication challenge ahead of them. Benefit design changes to financial factors such as deductibles and co-pays and the complex underwriting that may result in premium increases are difficult to explain to employees and plan participants.

Medical Management

- The regulations make it clear that medical management tools may be used to manage benefits but prohibit their more stringent application in the review of MH/SUD benefits. Without defining *“generally accepted medical criteria”*, the regulations leave room for interpretation that may result in conflicting practices, as competing plans in a single state may issue very different criteria, resulting in a provider treating two very similar patients, each with a different insurer, in differing ways. Establishing professional and facility standards such as credentialing is left to States and health plans where variability already exists. This issue is directly related to the scope of services issue discussed above.
- The regulations do not expressly encourage efforts to better integrate primary and behavioral healthcare. The MHPAEA could enhance Behavioral Medicine, Patient-Centered Healthcare/Medical Homes, early screening, assessment and referral efforts, as well as the treatment of co-morbid chronic conditions however the IFR does not address these issues. Primary care physicians still struggle to bill for more than one encounter per day making integrated care in a single setting on a same-day basis difficult. Ironically, this is the type of care from which many patients would derive the most benefit, helping to drive down the costs associated with less effective care and non-compliance with treatment.
- Standardized SUD assessment instruments and patient placement criteria are important tools for the provision of cost-effective and equitable treatment. The IFR could do more to help guide stakeholders toward an appropriate common ground. Because plans, payers and providers may not readily agree upon generally accepted medical criteria, the regulations provide an opportunity to bring best practices

and scientifically-validated practices to the attention of stakeholders and promote the use of instruments that have been demonstrated most valid and reliable. Identifying specific SUD assessment tools and patient placement criteria would help to ensure that people receive the most appropriate treatment. Simply pointing to the DSM-IV and ICD-9 is not adequate in all instances.

Opportunities

Integration

The advent of the MHPAEA represents a unique opportunity in time to pursue better integration in a system of care that has been defined by fragmentation for too long. Integrative opportunities lie ahead for the following stakeholders:

- *Mental health and substance use disorder service providers* who can work more closely together for the purpose of treating co-occurring disorders.
- *Behavioral health providers of all kinds* who share common operational, information technology, quality and business aspirations. This opportunity involves both “horizontal” and “vertical” integration and alliance building.
- *Health plans, managed behavioral health organizations, pharmacy benefit managers, and disease management firms* who can integrate on a number of different levels to share processes, information and raise the overall quality of care as a result.
- *Medical and behavioral health care managers* who can see to it that the “whole person” is treated. Co-morbid conditions such as diabetes respond well to integrated efforts, which produce cost savings and improved outcomes.
- *Primary care and behavioral healthcare providers* who want to treat the whole person, particularly where co-morbid conditions are concerned.
- *Publicly-funded mental health and substance abuse disorder programs and commercial health plans* who realize that the effective treatment of serious mental illness, serious emotional disturbance in children and substance use disorders require the integrated assets and efforts of the community and health economy. The opportunity to “blend” and “braid” systems of care is excellent as a result of the MHPAEA.
- *Health plans* can bring into their advisory and governance structures the perspective and consultation of organizations representing those with various mental health and substance use disorders, further legitimizing their allocation of scarce healthcare dollars to this constituency and better integrating their care.

Patient-Centered Medical Home Initiatives

The PCMH initiatives unfolding around the country are vigorously championed by healthcare professionals, managed care, researchers, employers and policymakers as having tremendous potential for the future of our healthcare system. Among other positive developments, the creation of medical and healthcare “homes” with primary care physicians at their center enable the early screening and detection of co-morbid conditions among people at high-risk for chronic illness. These models also feature tremendous advances in the tracking and monitoring of patient progress. By cooperating and collaborating in these models, all stakeholders have a great deal to gain. The coordination of care, sharing of vital health information that prevents errors and assures patient safety, and ease of navigation patients enjoy through otherwise complex systems of care produces greater clinical outcomes and bottom-line savings for payers.

Value Creation

Our healthcare system is at a juncture in its evolution that offers exciting opportunities for the creation of value. By focusing our collective efforts on continuous quality improvement, standardized health and quality of life outcomes measures such as those found in *Healthy People 2020*, and by virtue of creating rational

incentives for healthcare providers such as is the case in Pay-for-Performance programs, our healthcare and insurance system can begin to close the gap that has existed between our spending on healthcare and the resulting health outcomes we produce. Plans, payers and issuers can lead new initiatives to optimize access, quality and outcomes in the private sector while governmental agencies do the same (using the same metrics) in the public health sector.

All stakeholders should agree to the implementation of national best-practice guidelines for the prescribing and monitoring of psychiatric drug interventions, for example. Similarly, all stakeholders should agree to annual assessment of their performance in relation to the nationally accepted standard best-practice guideline they have chosen or that govern their particular discipline.

Health IT Adoption

Healthcare is the biggest and the last of our major business and economic sectors to “automate the shop floor”. There are many different programs, incentives and new initiatives dedicated to the advancement of electronic health records and health information exchange. As managed behavioral healthcare, State and County mental health and substance use disorder programs and all manner of behavioral health providers join their medical, hospital and health plan counterparts in a National Health Information Network linking vital information from coast-to-coast, the field will have overcome one of the greatest sources of its fragmentation.

Evidence-Based Treatment for the Seriously Mentally Ill (SMI)

Plans and payers can provide MHPAEA-compliant benefits for evidence-based treatment of the seriously mentally ill children and adults participating in their plans. To that end, MCOs and MBHOs can add providers who can deliver evidence-based modalities including: Child Psychiatrists and Psychologists; Targeted Clinical Case Management services; Assertive Community Treatment (ACT) programs; therapeutic nursery services; and therapeutic group home services.

Behavioral Health Benefit Management

Plans, payers, employers, issuers as well as State, County, and Medicaid programs can use this opportunity to assess the comparative advantages, benefits, issues and risks associated with a traditional carve-out, contemporary approaches to carve-in vendors and the complete absorption or in-sourcing of all roles, functions and responsibilities. This analysis does not advocate for one approach at the expense of another.

Conclusion

The Interim Final Rule and regulations provide a helpful start to clarifying the requirements for implementing the Mental Health Parity and Addiction Equity Act of 2008. The regulations have answered some key questions regarding deductibles, the role of EAPs, defined “substantially all” and “predominant”, and established that non-quantitative approaches to benefit management cannot be any more stringent for MH and SUD benefits than they are for medical benefits. As this report has discussed, however, the regulations have not yet defined scope of services or levels and types of care, and create very complex methods for determining benefits. Plans, issuers and payers have their work cut out for them in the coming months and many will discover that underwriting and carve-out agreements require considerable attention.

It is important to note that the IFR is, in fact, interim and that a 90-day comment period allows stakeholders to make their concerns known to the Departments. Similarly, it is important to recognize that this analysis is preliminary. While we have consulted experts from a number of disciplines, the real test of a Rule comes through its implementation. Only when we have been able to assess and review the impact of the regulations in a most practical sense will we be able to prepare a more conclusive analysis.

The MHPAEA Interim Final Rule was not released in a vacuum or a particularly calm time in America. We have endured a year of health insurance reform debate, two years’ deep recession, 10% unemployment, health plan membership losses, economic hardship for employers and households, and unparalleled state deficits that are threatening Medicaid and community behavioral healthcare budgets. The President’s recent budget illustrates what the publically-funded mental health and substance use disorder treatment fields can

anticipate. These dynamics underscore how interdependent the story behind and ahead of the MHPAEA truly is. All stakeholders should plan their approaches in a scenario-based and highly strategic manner.

An optimal behavioral healthcare system engages skilled care providers and stewards of finite health insurance resources in a cooperative effort to improve the health and well being of individuals who have entrusted the system with their taxes, premiums, minds and bodies. The consumer and plan member's wellbeing should be of primary concern. Achieving optimal health at a reasonable cost is an honorable endeavor that should distribute value equitably to the participants rather than producing winners and losers. Readers are strongly encouraged, therefore, to submit their comments, questions and concerns to the Departments on or before May 3, 2010. Doing so will help stakeholders protect themselves from the ambiguities that riddle IFR; minimize costs in implementation; and maximize the positive intent and effect of the law.

About the AHP Consulting Group

The AHP Consulting Group is dedicated to improving the delivery of effective mental health and addictions coverage and treatment. Our consulting services are relevant to all segments of the healthcare and health insurance industries and are designed to enhance business operations, data management and access to person-centered services. Our clients include Federal, State and County agencies, employers and their health plan administrators, managed care companies as well as behavioral health delivery systems and providers of all kinds.

Since our founding in 1980, AHP's services have evolved to help clients identify and define challenges and potential solutions; engage stakeholders; design or modify programs and organizational practices; provide training; and develop new resources. AHP also conducts research on difficult issues, evaluates programs and service systems, and helps clients translate research into practice.

AHP consultants are senior subject matter experts who have earned their "thought-leader" status over 20-30 year careers by developing and managing high-performance systems of behavioral healthcare. The insights they bring to large national projects are informed by diverse experience in the field. AHP is especially known for connecting the dots across disciplines, service systems, funders, and populations to develop comprehensive real-world solutions that meet the needs of consumers and providers. AHP has primary offices in Sudbury, MA (near Boston); Albany, NY; Germantown, MD (near Washington, D.C.) and Palm Desert, CA while many other consultants are located nationwide.

About the Legal Action Center

The Legal Action Center is the only non-profit law and policy organization in the United States whose sole mission is to fight discrimination against people with histories of addiction, HIV/AIDS, or criminal records, and to advocate for sound public policies in these areas.

For three decades, LAC has worked to combat the stigma and prejudice that keep these individuals out of the mainstream of society. The Legal Action Center is committed to helping people reclaim their lives, maintain their dignity, and participate fully in society as productive, responsible citizens.